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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/914,152      | 08/24/2001  | Hisashi Narimatsu    | 2139.25             | 1765             |

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EXAMINER

RAO, MANJUNATH N

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/914,152

Applicant(s)

NARIMATSU ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

Claims 1-47 are currently pending in this application.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-13, 26-27, drawn to polypeptides, polynucleotides, vectors, host cells, method of making the polypeptide and method of using the polynucleotide.

Group II, claim 14-15, drawn to a process of producing the polypeptide by breeding a non-human transgenic animal.

Group III, claim 16, drawn to a process of producing the polypeptide by culturing a transgenic plant.

Group IV, claim 17, drawn to a process of producing the polypeptide by synthesizing the polypeptide in an *in vitro* transcription translation system.

Group V, claim 18, 23 drawn to a process for producing a reaction product having galactose using the polypeptide as enzyme source and using an acceptor substrate selected from a group consisting of N-acetylglucosamine, an oligosaccharide having N-acetylglucosamine at the non-reducing terminus thereof and a complex carbohydrate having N-acetylglucosamine at the non-reducing end as an acceptor along with UTP in the reaction.

Group VI, claim 19, 23 drawn to a process for producing a reaction product having galactose using the polypeptide as enzyme source and using an acceptor substrate selected from a group consisting of glucose, an oligosaccharide having glucose at the non-reducing terminus thereof and a complex carbohydrate having glucose at the non-reducing end along with UTP in the reaction.

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Group VII, claim 20, 23 drawn to a process for producing a sugar chain or a complex carbohydrate by culturing the transformant selected from a microorganism, an animal cell, a plant cell or an insect cell.

Group VIII, claim 21, 23, 24 drawn to a process for producing a sugar chain or a complex carbohydrate by breeding the non-human transgenic animal.

Group IX, claim 22, drawn to a process for producing a sugar chain or a complex carbohydrate by culturing the transgenic plant.

Group X, claim 25 and 29, drawn to a method for determining expression level of a gene encoding the polypeptide.

Group XI, claim 28, drawn to polynucleotides with SEQ ID NO:20 or 21.

Group XII, claim 30, drawn to a method of detecting cancer.

Group XIII, claim 31, drawn to a method for inhibiting transcription using the DNA.

Group XIV, claims 32-36, drawn to antibody and its use.

Group XV, claim 37, drawn to a method for screening a compound which modulates the activity of the polypeptide.

Group XVI, claim 38-39, drawn to a method for screening a compound which modulates the expression of the gene.

Group XVII, claims 40-43, drawn to a promoter DNA governing the transcription of a gene.

Group XVIII, claims 44-45, drawn to a method for screening a compound which modulates the activity of the promoter DNA.

Group XIX, claims 46-47, drawn to a knock-out non-human animal.

The inventions listed as Groups I-XIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall

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consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited products polypeptide and polynucleotides encoding them. Further, pursuant to 37 C.F. R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-XIX, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



Manjunath N. Rao

February 6, 2003

**MANJUNATH RAO**  
**PATENT EXAMINER**